

## II. **REMARKS**

This Amendment is filed with a Request for Continued Examination, and in response to the Office Action dated February 25, 2008, with the appropriate fees.

Applicants thank the Examiner for the courtesy extended to Applicants' representative in the telephone interview of July 29, 2008.

Claims 13-15, 17-21, and 23-36 are pending.

By this Amendment, claims 13, 21, and 25 are amended, and claims 17, 23, 28, and 29 are canceled. Support for the amendment can be found in the specification and claims as original filed. For example, support for the amendment to claims 13, 21, and 25 can be found in the specification on page 19, Table 2, and line 20; page 20, Table 3, and lines 1 and 18; and page 24, Table 4. Applicants submit that no new matter has been added and respectfully request reconsideration and withdrawal of the pending rejection.

### **Rejection under 35 U.S.C. § 102(b) over Lambiase**

Claims 13-15, 17-21, and 23-36 were rejected under 35 U.S.C. § 102(b) over Lambiase (WO 98/48002). Applicants traverse the rejection.

Claim 13 of the presently claimed invention is directed to a "method for the treatment of a pathology affecting internal tissues of an eye, comprising identifying a subject in need of treatment of a pathology affecting internal tissues of an eye, topically applying a composition comprising from 10 to 500 µg/ml of nerve growth factor over an ocular surface of a subject in need thereof... wherein the pathology is selected from the group consisting of: cataract, scleromalacia, perforating trauma of the sclera, optic neuritis, maculopathy, retinitis pigmentosa, myopic retinopathy, macular foramen, uveitis, vitrectomy, ocular hypotonia, and phthisis" (emphasis added). Claims 14-15, and 18-20 depend from independent claim 13.

Claim 21 is directed to a "method for the treatment of a pathology affecting internal tissues of an eye, comprising identifying in a subject in need of treatment of a pathology affecting internal tissues of an eye, topically applying a composition comprising nerve growth factor over an ocular surface of the subject in need thereof...

wherein the pathology is selected from the group consisting of: cataract, scleromalacia, perforating trauma of the sclera, optic neuritis, maculopathy, retinitis pigmentosa, myopic retinopathy, macular foramen, uveitis, vitrectomy, ocular hypotonia, and phthysis" (emphasis added). Claim 24 depends from independent claim 21.

Claim 25 of the presently claimed invention is directed to "method for the treatment of a pathology affecting internal tissues of an eye, comprising identifying a subject in need of treatment of a pathology affecting internal tissues of an eye, topically applying a composition comprising from 200 to 500 µg/ml of nerve growth factor over an ocular surface of a subject in need thereof... wherein the pathology affecting the internal tissues of the eye of the subject in need thereof; wherein the pathology is selected from the group consisting of: cataract, scleromalacia, perforating trauma of the sclera, optic neuritis, maculopathy, retinitis pigmentosa, myopic retinopathy, macular foramen, uveitis, vitrectomy, ocular hypotonia, and phthysis" (emphasis added). Claims 26-36 depend from independent claim 25.

Claims 17, 23, 28, and 29 have been canceled.

In contrast to the presently claimed invention, Applicants submit that Lambiase merely discloses the "use of nerve growth factor for the storage of corneas in culture, the *in vitro* production of corneal and conjunctival tissues and the treatment of corneal and conjunctival diseases" (Lambiase, page 1, lines 5-7) (emphasis added). Applicants submit that Lambiase merely discusses the treatment of conditions relating to the cornea and conjunctiva, which are not the pathologies listed in amended independent claims 13, 21, and 25.

Applicants submit that the pathologies listed in amended independent claims 13, 12, and 25 are pathologies which affect the internal tissues of the eye. For example, Applicants submit that cataracts are characterized by an opacity of the crystalline lens which are often caused by morphological, biochemical, and molecular changes of the lens. Applicants submit that nerve growth factor is able to reach the lens even when applied topically. Further, Applicants submit that scleromalacia and perforating trauma of the sclera affect the sclera, an internal tissue. In addition, optical neuritis, which involves degeneration of the axons of the retinal ganglion cells; maculopathy, which

involves degeneration of the retinal cells located in the macular; and retinitis pigmentosa, which involves degeneration of the retinal photoreceptors, involve the retina and optic nerve, which are internal tissues. In addition, uveitis and vitrectomy relate to the choroid, which is an internal tissue, and ocular hypotonia and phthisis involve impairment of aqueous humor production by the ciliary body, which is an internal tissue.

Applicants respectfully disagree with the Examiner's position that Lambiase anticipates the presently claimed invention. Applicants submit that in the present application, the disclosure of the treatment of conditions involving the cornea and conjunctiva does not render the treatment of conditions involving the internal tissues of the eye inherent.

Applicants resubmit that this position is supported by the case law, and in particular, Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368 (Fed. Cir. 2005). In Perricone, the Court of Appeals for the Federal Circuit ("the Federal Circuit") addressed the issue of anticipation by inherency and method of use claims. Applicants submit that the Perricone case is analogous to the present application. Applicants note the following passage in Perricone.

"The issue is not, as the dissent and district court imply, whether Pereira's lotion if applied to skin sunburn would inherently treat that damage, but whether Pereira discloses the application of its composition to skin sunburn. It does not... New uses of old products or processes are indeed patentable subject matter." *Id.* at 1378.

The Federal Circuit continued:

"[The claim directed to the treating skin sunburn] recites a new use of the composition disclosed by Pereira, i.e., the treatment of skin sunburn. The district court's inherent anticipation analysis for this claim contains a flaw. The disclosed use of Pereira's lotion, i.e., topical application, does not suggest application of Pereira's lotion to skin sunburn. In other words, the district court's inherency analysis goes astray because it assumes what Pereira neither disclosed nor rendered inherent. Because Pereira does not disclose topical application *to skin sunburn*, this court reverses the district court's holding that Pereira anticipates claims 1-4 and 7 of the '693 patent." *Id.* at 1378-1379.

Applicants respectfully disagree with the Examiner's assertions that Lambiase teaches the same method steps as the presently claimed invention. Applicants remark that the present claims involve the step of "identifying a subject in need of treatment of a pathology affecting internal tissues of an eye... wherein the pathology is selected from the group consisting of: cataract, scleromalacia, perforating trauma of the sclera, optic neuritis, maculopathy, retinitis pigmentosa, myopic retinopathy, macular foramen, uveitis, vitrectomy, ocular hypotonia, and phthisis." (claims 13, 21, and 25). Applicants submit that although Lambiase may disclose application of nerve growth factor to the eye, it does not teach or suggest the application in a subject affected by pathologies of the internal eye, much less the specific pathologies recited in the presently amended claims. Applicants disagree with the Examiner's assertion that Lambiase and Finkenaar, which is discussed below, treat the "same patient population that applicants includes in their claims" (Office Action, page 5), because patients having the recited pathologies in the claims do not necessarily have the corneal and conjunctival pathologies disclosed in the reference.

Applicants submit that the holding in Perricone v. Medicis Pharmaceutical Corp. is relevant and analogous to the present application. Like in Perricone, Applicants submit that the applied reference (in this case, Lambiase) does not teach the use of the disclosed compound for treatment of the claimed conditions. Similar to what the Federal Circuit stated in Perricone, the issue is not whether nerve growth factor, *if* applied to eyes afflicted with the recited pathologies, would inherently treat those conditions. Rather, the issue is whether Lambiase *discloses* the use of nerve growth factor to treat the conditions. Applicants respectfully submit that Lambiase does not, and therefore the rejection over Lambiase is improper.

For at least the above reasons, Applicants submit that Lambiase does not teach each and every element of the presently claimed invention, inherently or otherwise. As such, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 13-15, 17-21, and 23-36 under 35 U.S.C. § 102(b) over Lambiase.

Rejection under 35 U.S.C. § 102(b) over Finkenaar et al.

Claims 13-15, 18-19, 21, 24-28, and 30-36 were rejected under 35 U.S.C. § 102(b) over Finkenaar et al. (EP 0312208). Applicants traverse the rejection.

Independent claims 13, 21, and 25 have been discussed above. Claims 14, 15, and 18-20 depend from claim 13. Claim 24 depends from claim 21. Claims 26-27 and 30-36 depend from claim 25.

Applicants submit that Finkenaar et al. merely discloses “aqueous gel formulations or viscous solutions for the controlled delivery of growth factors to a wound site” (Finkenaar et al., page 2, lines 36-37). In particular, Finkenaar et al. discloses “gels for topical or incisional wound healing, gels for healing wounds in the anterior chamber of the eye and low viscosity, aqueous formulations for those applications requiring a more fluid formulation having a higher water content” (Finkenaar et al., page 2, lines 38-40). Finkenaar et al. discloses, “Wounds that may be healed using the compositions of the present invention are those which result from any accidental or medical injury which causes epithelial damage such as ophthalmic wounds which result from corneal ulcers, radiokeratotomy, corneal transplants, epikeratophakia and other surgically induced wounds in the eye; and cutaneous wounds such as burn wounds, incisional wounds, donor sit wounds from skin transplants, and ulcers...” (Finkenaar et al., page 6, lines 4-7).

As asserted previously, Applicants submit that Finkenaar et al. discloses procedures or conditions involving the cornea, and not the internal tissues of the eye. Further, Applicants submit that Finkenaar et al. does not teach or suggest the recited pathologies of the present claims.

Applicants again respectfully disagree with the Examiner’s assertion that “inherently, the composition advanced by Finkenaar et al., when applied to the eye, treats the same eye-related disorders as the instant application” (Office Action, page 4, first paragraph). Similar to the above rejection over Lambiase, Applicants submit that the assertion that Finkenaar et al. inherently anticipates the presently claimed invention is improper. Applicants submit that the Federal Circuit’s decision in Perricone v. Medicis

Pharmaceutical Corp. also applies to the current rejection. Applicants submit that the issue is whether Finkenaur et al. discloses the use of nerve growth factor to treat the claimed conditions, and Applicants submit that Finkenaur et al. does not. Therefore, Applicants respectfully submit that Finkenaur et al. does not anticipate the presently claimed invention.

Further, like Lambiase, Finkenaur et al. does not teach or disclose the step of identifying a subject in need of treatment of a pathology affecting internal tissues of an eye... wherein the pathology is selected from the group consisting of: cataract, scleromalacia, perforating trauma of the sclera, optic neuritis, maculopathy, retinitis pigmentosa, myopic retinopathy, macular foramen, uveitis, vitrectomy, ocular hypotonia, and phthisis." (claims 13, 21, and 25).

For at least the above reasons, Applicants submit that Finkenaur et al. does not teach or suggest all of the elements of the presently claimed invention, inherently or otherwise. As such, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 13-15, 18-19, 21, 24-28, and 30-36 were rejected over Finkenaur et al.

## II. CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this response is not timely filed, the Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other additional fees which may be required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 026073-00020.

Respectfully submitted,



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